

## REMARKS

Presently, claims 1, 8 to 19 are being prosecuted. Claims 3, 4, and 7, are withdrawn. Claims 2, 5 and 6 are canceled. This differs from the initial report by the examiner. Based on the specific election as described by the examiner in the last paper, claims 9 and 10 required amendments, herein provided, to conform with the restriction, and if claims 12-17 were prosecutable, then claims 9-11 are as well when restricted to agree with the terms used by the examiner.

First to clarify, the election is to a parachute structure of cyclodextrin (specification and prior art reference) not "cyclodextran" and the spacer of first choice is selected from beta-amino acids or gamma-amino butyric acid in contrast to the examiner's notes in item 1 page 2.

### Rejections under 35 U.S.C. 112, second paragraph

The Examiner rejected all claims under 35 U.S.C. 112, second paragraph for the reasons noted in paragraph 2 of the office action on page 2.

As to claim 1, the Examiner notes that it seems incomplete with respect to "preselected defined distance from the membrane within cells" since it is unclear what role the complex plays in the defining this distance.

Claim 1 has been amended to specify that a cyclodextrin is the hydrophilic moiety to which the therapeutic agent is attached. It is the structure of the hydrophilic cyclodextrin which functions as the parachute and does not permit the therapeutic to travel far away from the cell membrane. When a spacer is also used, it will define with the cyclodextrin the action diameter.

Because hydrophilic moiety is now selected in claim one as a cyclodextrin the descriptions of claims 2 to 4 are either unnecessary or in conflict with this selection for the parachute structure. So they are withdrawn from prosecution. Claim 5 is essentially incorporated into claim 1 and thus it is canceled.

The general placement of the therapeutic compound of the complex within the cell, yet at the cell membrane has been moved to the new dependent claim 19.

Rejections under 35 U.S.C. 112, first paragraph

The Examiner rejected Claims 1 to 2, 5 to 6, 8, and 12 to 18 under 35 USC 112, first paragraph, for the reasons noted in paragraph 3 of the Office Action starting on page 3.

In reply to the examiner's concerns, portions of claims 2, 5 and 6 were incorporated into amended claim 1 so as to provide the structure for the general terms of "parachute structure" and "therapeutic compound".

Claim 1 is allowable as amended and especially so in light of the parent application being an issued patent, US 6,806,284, with complimentary claim language to the now amended claims.

Rejections under 35 U.S.C. 102(b)

The Examiner rejected claims 1 to 2, 5 to 6, 8, and 12 to 18, under 35 U.S.C. 102(b), as being anticipated by Ruebner et al. (J. of Inclusion Phenomena...), including the present inventor, for the reasons noted in paragraph 4 on Page 7 of the office action.

The Ruebner et al. reference describes the process of synthesizing  $\beta$ -cyclodextrin dimers as shown on page 36, Scheme 1, complex 8a at the bottom. It is noted on page 35 that "Cyclodextrins are known to form stable inclusion complexes with porphyrinoid photosensitizers." This tells us that porphyrin photosensitizers can be bound within cyclodextrin dimers, as inclusion compounds and thereby protected from preliminary exposure to body chemistry and attachment to tissue before the porphyrin reaches a desired treatment site. The study was to determine at what spacer length would be optimal for use of the dimer as a carrier.

In the present invention significantly the photosensitizer is bound directly to one (1) cyclodextrin compound or indirectly to a cyclodextrin compound. Neither case is proposed nor suggested as a useful structure for photosensitizers or PDT. The use of

dimers for inclusion compounds generally teaches one skilled in the art that an exposed photosensitizer attached to one (1) cyclodextrin would not be a wise choice for well controlled PDT treatments. Photosensitizers bound to 1 cyclodextrin through a spacer would be predicted to be even less desirable, based this publication.

The ability and benefit of adding the biotin-avidin vector for targeting is not a differentiating aspect of the present invention but indeed uses the information gathered by the inventor and his co-workers, for Ruebner et al. in the SPIE article cited by examiner. Indeed this paper is primarily about establishing that multiple biotin-avidin containing species bounded to photosensitizers could enhance activity of the photosensitizers by bringing a number of photosensitizers to a previously activated cell surface. In the present invention this knowledge is extended to apply to complexes of cyclodextrin and a photosensitizer. It is not anticipated by the disclosure in the SPIE article nor in combination with the J. of Inclusion Phenomena..... article.

Thus the Ruebner et al. articles do not make obvious the use of the biotin-avidin for vectoring purposes, although it is not critical to the novelty and non-obviousness of the basic claims for the present invention. It merely is a combination of separate work by the inventor's group in cyclodextrin dimers, biotin-avidin multiple complexes, and possible use in PDT treatments. Nor does the examiner explain in which one or where they actually bear on the basic independent claim or others of the present invention.

Double Patenting Rejection:

With the amended claim 1 there no longer is any potential overlap with the issued claims from the parent application. In fact the amended claim covers complimentary structures which were excluded by withdrawal/election of the parent application as it was prosecuted.

With these changes and remarks, it is believed that the application is now in condition for allowance and reconsideration is respectfully requested. An early and favorable response is earnestly solicited. Thank you.

Appl. No 09/745,458

BJA272C

Reply to Office Action dated 2/7/2006

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Bolesh J. Skutnik". The signature is fluid and cursive, with the first name "Bolesh" being more prominent than the last name "Skutnik".

Bolesh J. Skutnik, PhD, JD

Reg. No. 36,347

Attorney for Applicants

Dated: June 7, 2006

CeramOptec Industries, Inc.

515 Shaker Road

East Longmeadow, MA 01028

Phone: (413) 525-8222

Fax: (413) 525-0611

BJA/sec